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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/913,435

02/02/2002

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RU-0130

9557

26259 7590 12/21/2006
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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT

PAPER NUMBER

1614

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

12/21/2006

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/913,435

Applicant(s)

YURKOW ET AL.

Examiner

Phyllis G. Spivack

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1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/9/06; 9/25/06.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicants' Reply filed September 25, 2006 and Reply filed October 9, 2006, following a Notice of a noncompliant amendment, are acknowledged. Claims 1 and 5 remain under consideration.

Claim 1 was rejected under 35 U.S.C. 112, first paragraph in the last Office Action, as failing to comply with the written description requirement. The claim contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, that Applicants had possession of the claimed invention. No reference to the specification was provided by Applicants as to support for the recitation "non-viral" cells. See *In re Rasmussen*, 211 USPQ 323.

Applicants argue nowhere in the specification as filed is there any reference to contact of viral cells and urge that one of skill would understand that the instant invention always involves non-viral cells.

Applicants' argument is not found persuasive. The rejection of claim 1 under 35 U.S.C. 112, first paragraph, in the last Office Action, as failing to comply with the written description requirement, is maintained. The amendment to claim 1 filed August 23, 2005 lacks support in the specification.

In the last Office Action claims 1 and 5 were rejected under 35 U.S.C. 102(b) as being anticipated by Qiu et al., The Journal of Biological Chemistry. It was asserted Qiu teaches a method of stabilizing or maintaining the redox state of hyperproliferative human colonic carcinoma cells, cell line HCT116, by contacting said cells with

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chemotherapeutic agents, aziridinybenzoquinones (AZQ), as required by claim 1, and a redox clamping agent, N-acetylcysteine (NAC).

Applicants argue Qui teaches decreasing the desired effect of the chemotherapeutic agent and fails to teach sensitizing non-viral cells to the effects of a chemotherapeutic agent using a redox-clamping agent.

Applicants' argument is persuasive with respect to claim 1, and the rejection of record under 35 U.S.C. 102(b) is withdrawn with respect to claim 1. However, the rejection is maintained over claim 5 because each limitation of the claim is met by the reference.

Qui teaches stabilization of abnormal fluctuations in the redox state comprising contacting hyperproliferative cells of the colon cancer cell line HCT 116 with the sulfhydryl-containing redox clamping agent such that the cells are maintained in a specific redox state without abnormal fluctuations associated with abnormal cell growth. See page 31917, column 2, line 36. In claim 5 "stabilizing" is broadly interpreted as holding steady, maintaining or limiting fluctuations; "abnormal" is broadly interpreted as "deviant or irregular; "specific" is broadly interpreted as particular or distinctive.

See page 31917, column two, under *Effects of N-acetylcysteine on Free Radical Production by HCT116 cells*. In this model involving abnormal cell growth or proliferation, redox cycling is described. The effect of N-acetylcysteine on free radical production by the quinones suggests an effective transfer of the radical character from an oxygen-centered radical to a less reactive sulfur-center radical in Reaction 2.

No claim is allowed.

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No claim is allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not filed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this Final Action.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ardin Marschel, can be reached 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

December 15, 2006


Phyllis Spivack

**PHYLLIS SPIVACK
PRIMARY EXAMINER**